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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,256	12/18/2003	James E. Dahlberg	FORS-08497	1902

7590 05/12/2005

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/740,256	DAHLBERG ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/18/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2 and 5-20, drawn to a method of hybridizing an miRNA to at least one nucleic acid, optionally to a second nucleic acid, to generate a detection structure, and detecting said detection structure, wherein said second nucleic acid is U6, classified in class 514, subclass 44. Upon election of this group, the claims are subject to an additional restriction as explained in the species election below.

II. Claims 1, 2 and 5-20, drawn to a method of hybridizing an miRNA to at least one nucleic acid, optionally to a second nucleic acid, to generate a detection structure, and detecting said detection structure, wherein said second nucleic acid is GAPDH, classified in class 514, subclass 44. Upon election of this group, the claims are subject to an additional restriction as explained in the species election below.

III. Claims 1, 3, 4, 5, 10, 12-14 and 17-19, drawn to a method of hybridizing an siRNA to at least one nucleic acid, optionally to a second nucleic acid, to generate a detection structure, and detecting said detection structure, wherein said second nucleic acid is U6, classified in class 514, subclass 44. Upon election of this group, the claims are subject to an additional restriction as explained in the species election below.

IV. Claims 1, 3, 4, 5, 10, 12-14 and 17-19, drawn to a method of hybridizing an siRNA to at least one nucleic acid, optionally to a second nucleic acid, to generate a detection structure, and detecting said detection structure, wherein said second nucleic acid is GAPDH, classified in class 514, subclass 44. Upon election of this group, the claims are subject to an additional restriction as explained in the species election below.

V. Claims 21-27 and 29-31, drawn to a kit comprising a nucleic acid configured for forming a detection structure when hybridized to a miRNA sequence, classified in class 514, subclass 44. Upon election of this group, the claims are subject to an additional restriction as explained in the species election below.

VI. Claims 21-24, 28 and 31, drawn to a kit comprising a nucleic acid configured for forming a detection structure when hybridized to a siRNA sequence, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The invention of group I is unrelated to the invention of group II. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. AlthoU6h each of the groups are drawn to a method of hybridizing an miRNA to at least one nucleic acid, optionally to a

second nucleic acid, to generate a detection structure, and detecting said detection structure, the groups each function by targeting a separate and structurally distinct target. Group I is drawn to U6, whereas group II is drawn to GAPDH. A search for one of these targets would not necessarily return art against the other target, due to the structural and functional differences of each. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups I and II are unrelated to the inventions of groups III and IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I and II are not disclosed as capable of use together and have different modes of operation than the inventions of groups III and IV. Groups I and II are drawn to miRNAs, whereas groups III and IV are drawn to siRNAs. As defined in the specification, miRNAs sequence-specifically control translation of target mRNAs by binding to sites of antisense complementarity in 3' untranslated regions. On the contrary, siRNAs function throU6h interacting with the RISC complex. A search for one of these inventions would not necessarily return art against another of the inventions, due to the structural and functional differences of each of the agents. To search more than one of these inventions in the same application presents a search burden.

The invention of group III is unrelated to the invention of group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. AlthoU6h each of the groups are drawn to a method of hybridizing an siRNA to at least one nucleic acid, optionally to a second nucleic acid, to generate a detection structure, and detecting said detection structure, the groups each function by targeting a separate and structurally distinct target. Group III is drawn to U6, whereas group IV is drawn to GAPDH. A search for one of these targets would not necessarily return art against the other target, due to the structural and functional differences of each. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups I-IV are each related to the inventions of groups V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid of the kit of groups V and VI can be used to inhibit expression of a target gene, which does not involve forming and screening for detection structures. The inventions of groups I-IV involve separate considerations from the inventions of groups V and VI and would require a separate search. To search one of the inventions would not necessarily return art against the other.

The invention of group V is unrelated to the invention of group VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

806.04, MPEP § 808.01). In the instant case the inventions of groups V and VI are not disclosed as capable of use together and have different modes of operation. Group V is drawn to miRNAs, whereas group VI is drawn to siRNAs. As defined in the specification, miRNAs sequence-specifically control translation of target mRNAs by binding to sites of antisense complementarity in 3' untranslated regions. On the contrary, siRNAs function throU6h interacting with the RISC complex. A search for one of these inventions would not necessarily return art against another of the inventions, due to the structural and functional differences of each of the agents. To search more than one of these inventions in the same application presents a search burden.

Because the inventions are distinct for the reasons given above, and because a search for art against one group would not necessarily return art against another, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention: Claim 20 is drawn to miRNAs selected from the group consisting of Let-7, miR-1, miR-135, miR-15, miR-16, miR125b, miR-1d and miR124a. Claim 29 is drawn to miRNAs selected from the group consisting of Let-7, miR-1, miR-

135, miR-15, miR-16, miR1b, miR-124a and miR124b. Each of the miRNA sequences are structurally distinct, sharing no common core. Each sequence is considered a separate and distinct invention. Upon election of group I, II, or V, applicant is required to further elect one species from claim 20 or 29, consonant with the elected invention.

Additionally, claims 10, 12 and 13 are drawn to various species of detection assays. Each assay has different method steps and mode of operation. The claims are drawn to invasive cleavage assays, rolling circle replication assays, sequencing assays, polymerase chain reaction assays, hybridization assays, hybridization assays employing a probe complementary to a mutation, microarray assays, bead array assays, primer extension assays, enzyme mismatch cleavage assays, branched hybridization assays, NASBA assays, molecular beacon assays, cycling probe assays, ligase chain reaction assays, invasive cleavage structure assays, ARMS assays, and sandwich hybridization assays. Upon election of groups I, II, III or IV, applicant is required to further elect one assay for examination.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755. The examiner can normally be reached on Mon-Fri 7:00 am – 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
Art Unit 1635

JAMES SCHULTZ
PATENT EXAMINER